MAY 2 3 2000



# Special 510(k) - Device Modification
# Summary of Safety and Effectiveness for the Howmedica Osteonics® Xia Hook Components of the Xia Spine System

## Submission Information

**Name and Address of the Sponsor of the 510(k) Submission:**

Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677

**Contact Person:**

Mary-Catherine Dillon
Regulatory Affairs Specialist

**Date of Summary Preparation:**

April 25, 2000

## Device Identification

**Proprietary Name:** Xia Spine System

**Common Name:** Spinal Fixation Appliances

**Classification Name and Reference:** Spinal Interlaminal Fixation Orthosis
21 CFR §888.3050

## Predicate Device Identification

The subject hook components are substantially equivalent to the hook components of the following cleared devices:

Xia Spine System (K982494, K984251)
Osteonics® Spinal System (K951725)

## Device Description

The additional hooks being offered as part of the Xia Spine System are: medium pedicle hooks, left angled offset hooks, right angled offset hooks, left straight offset hooks, right straight offset hooks, and extended-body lumbar hooks. The basic designs of the new hooks are already offered as part of the Xia System. The locking mechanisms for the subject hooks are identical to that of the current

Xia hooks. The blade portions of the new hook components are identical to the blade portions of the Osteonics Spinal System hooks.

The subject hooks will be manufactured from the same material (Ti6AL4V ELI alloy) and will have the same indications as the predicate Xia hooks.

**Intended Use:**
As with the predicate hooks, the subject hooks are single use devices for implantation as part of the Xia Spine System. Specific indications follow.

**Indications:**
The XIA Spine System is intended for use in the noncervical spine. When used as a pedicle screw fixation system, the XIA Spine System is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

When used as a pedicle screw fixation system, the XIA Spine System is also intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used an anterior screw fixation system or a posterior hook and sacral/iliac screw fixation system, the XIA Spine System is indicated for patients with degenerative disc disease which is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis or revision of failed fusion attempts.

**Performance Data:**
An engineering analysis has been conducted to demonstrate the substantial equivalence of this Howmedica Osteonics hook design to predicate hook designs in terms of its fatigue strength.

**Statement of Technological Comparison:**
The subject components are substanitally equivalent in terms of design, material and indications for use as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2000

Ms. Mary Catherine Dillon
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07601-1677

Re: K001319
Trade Name: Xia Spinal System
Regulatory Class: II
Product Code: MNH, MNI and KWQ
Dated: April 25, 2000
Received: April 26, 2000

Dear Ms. Dillon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001319

Device Name: Xia Hooks , Xia Spine System

The Xia Hooks are intended to be used as part of the Xia Spine System.

Indications For Use:

The XIA Spine System is intended for use in the noncervical spine. When used as a pedicle screw fixation system, the XIA Spine System is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

When used as a pedicle screw fixation system, the XIA Spine System is also intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used an anterior screw fixation system or a posterior hook and sacral/iliac screw fixation system, the XIA Spine System is indicated for patients with degenerative disc disease which is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis or revision of failed fusion attempts.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bachman

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001319

Prescription Use ✓ OR Over-The-Counter Use ___ (Per 21 CFR 801.109)
(Optional Format 1-2-96)